UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,045	01/28/2002	David S. Utterberg	435100	3924

27717 7590 12/18/2003

SEYFARTH SHAW
55 EAST MONROE STREET
SUITE 4200
CHICAGO, IL 60603-5803

EXAMINER	
DI NOLA BARON, LILIANA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,045	UTTERBERG ET AL.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *36-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-35, is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 36-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of copending Application No. 10/359045. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s), because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). (See In re Berg, 140 F.3d 1428, 46

USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985)). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods comprising applying an antibacterial fluid to a tubular medical cannula and antibacterial compositions. Instant claims 1-35 differ from claims 1-35 in the copending application in that instant claims 1-35 recite that the formulation has a viscosity of 5,000 to 80,000 cp, whereas copending claims 1-35 recite that the formulation has a viscosity of 5,000 to 150,000. The portion in the specification of the copending application that supports the recited range of viscosity in the instant claims includes two embodiments at pages 14 and 15 that would anticipate instant claims 1-35: specifically, one embodiment at page 14 of the copending application recites a preferred viscosity range of 20,000-50,000, and a second embodiment at page 15 of the copending application recites a viscosity range of 30,000-40,000. Claims 1-35 cannot be considered patentably distinct over copending claims 1-35 when there are specifically recited embodiments in the copending application that would anticipate claims 1-35. Alternatively, claims 1-35 cannot be considered patentably distinct over claims 1-35 of the copending application when there are specifically recited embodiments in the patent that support claims 1-35 of the instant application and fall within the scope of the claims, because it would have been obvious to one having ordinary skill in the art to modify the compositions disclosed in claims 1-35 in the copending application, by selecting a specifically disclosed embodiment in the application. One of ordinary skill in the art would have been motivated to modify the compositions claimed in the copending application because the embodiments are disclosed as preferred embodiments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 10, 11, 13-16, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dungman et al. (.S. Patent 5,335,373).

The patent provides a liquid antiseptic composition comprising a viscosity-modifying agent and having a broad spectrum antiseptic activity (See col. 11, lines 40-55 and col. 22, lines 60-65). With regard to claims 10, 15 and 20, the patent does not specifically teach the viscosity range claimed by Applicant, however, Dungman et al. teaches that the final viscosity of the composition may be more than 5,000 cp, and may have a high viscosity, like maple syrup (See col. 26, lines 14-22). Thus, the viscosity of the composition disclosed by the prior art is in the range claimed by Applicant.

With regard to claims 11 and 13, the patent includes ethanol, isopropanol, chlorhexidine and iodine among the antiseptic used in the compositions of the invention (See col. 22, lines 26-59).

With respect to claims 14, 16 and 21, the patent teaches that the viscosity modifier includes alkylated celluloses and starch (See col. 26, lines 14-46). The patent does not specifically teach the ratio between the antiseptic and the cellulose, however, one of ordinary skill in the art would have been capable to determine the optimal ratio by routine experimentation.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Dangman et al. to devise antibacterial compositions having high viscosity. The expected result would have been a successful composition. Because of the teachings of Dangman et al., that the antiseptic composition may be designed to have a broad spectrum activity against pathogens, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful against infections. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

7. Claims 1-9, 17-19, 22-30 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al. (U.S. Patent 5,997,524) in view of Dangman et al. (U.S. Patent 5,335,373).

Burbank et al. discloses catheters capable of delivering antiseptics to a percutaneous penetration site through which the catheter is attached to the implanted port (See col. 2, lines 55-65). With regard to claims 1, 8, 23, 27, 29 and 30, Burbank et al. teaches that a compressible element in the catheter is impregnated with the antiseptic agent, and the agent is released from the

compressible element when the element is compressed against the skin of the patient upon percutaneous insertion of the access tube into an implanted port (See col. 3, lines 19-34). Additionally, the patent teaches that the ability of the catheter to deliver antibacterial drugs to the penetration site is advantageous in inhibiting infection while the catheters are connected to the port for prolonged periods of time and enhances the safety of the patient (See col. 2, line 65 to col. 3, line 8). Thus, Burbank et al. provides a method comprising applying an antibacterial fluid to a tubular cannula. Burbank et al. is deficient in the sense, that the patent does not specify the viscosity of the fluid.

With respect to claims 3-4, Burbank et al. teaches that the compressible element may be saturated with the liquid active agent, so that the liquid is released immediately when the tube is introduced, and the remaining amount is released more slowly while the tube remains in place (See col. 5, lines 54-59). Since the antibacterial liquid is released immediately as a bolus, it would have been obvious to one of ordinary skill in the art that part of the liquid would run on the outer wall of the cannula. Additionally, Burbank et al. teaches that the liquid agent will spread over the surface of the skin and will penetrate at least partly into the tissue tract formed by the access needle when it enters the aperture in the patient's skin (See col. 6, lines 42-45).

Regarding claims 9, 28 and 32, Burbank et al. teaches that the catheter of the invention may be packaged together with instructions for use in a kit (See col. 6, lines 54-64).

With regard to claims 17-19 and 22, the compressible element disclosed by Burbank et al. is a squeeze-delivery container (See col. 3, lines 19-25). The patent teaches that the compressible element is attached to the distal end of the fitting in the catheter body (See col. 5, lines 40-45), and the access tube has a lumen, which can be larger than 2.08 mm (See col. 5, lines 14-25). Burbank et al. is deficient in the sense, that the patent does not specify the viscosity of the fluid.

With respect to claims 33-34, Burbank et al. teaches that the liquid agent will spread over the surface of the skin and will penetrate at least partly into the tissue tract formed by the access needle when it enters the aperture in the patient's skin (See col. 6, lines 42-45). It would have been obvious to one of ordinary skill in the art that spreading of the antiseptic composition over the skin would also imply spreading of the composition over the outer surface of the cannula. Burbank et al. is deficient in the sense, that the patent does not specify the viscosity of the fluid.

With regard to claim 35, the patent teaches that the polymeric tubes in the catheter body include a lumen connected to a fitting, and the access tube, typically a needle, extends distally from the side of the fitting (See col. 5, lines 1-40 and claims 1-2).

Regarding claims 2, 5-7 and 24-26, Burbank et al. is deficient in the sense that the patent does not specify the antibacterial agent used in the composition of the invention and the viscosity properties of said composition.

Dangman et al. provides a liquid antiseptic composition comprising a viscosity-modifying agent and having a broad spectrum antiseptic activity (See col. 11, lines 40-55 and col. 22, lines 60-65). The patent does not specifically teach the viscosity range claimed by Applicant, however, Dungman et al. teaches that the final viscosity of the composition may be more than 5,000 cp, and may have a high viscosity, like maple syrup (See col. 26, lines 14-22). Thus, the viscosity of the composition disclosed by the prior art is in the range claimed by Applicant.
With regard to claim 2, Dungman et al. includes surfactants in the composition of the invention (See col. 24, lines 1-63). Some of the surfactants cited by the prior art, such as magnesium aluminum silicate, are also lubricants, thus the composition would reduce friction, as claimed by Applicant.

With respect to claims 5-7 and 24-26, the patent provides a liquid antiseptic composition comprising a viscosity-modifying agent (See col. 11, lines 40-55), and includes isopropanol among the antiseptic used in the compositions of the invention (See col. 22, lines 26-59), and alkylated celluloses and starch among the viscosity modifiers (See col. 26, lines 14-46).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to devise methods of applying antibacterial compositions by applying the antiseptic compositions disclosed by Dangman et al. to the catheters provided by Burbank et al. The expected result would have been successful methods of producing antibacterial implant devices. Because of the teachings of Burbank et al., that catheters may be equipped with antiseptic compositions, and the teachings of Dangman et al., that the antiseptic composition may

be designed to have a broad spectrum activity against pathogens, one of ordinary skill in the art would have a reasonable expectation that the methods claimed in the instant application would be successful against the spread of infections. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dangman et al. as applied to claims 10, 11, 13-16, 20 and 21 above, and further in view of Moenning (U.S. Patent 6,063,060).

The teachings of Dangman et al. have been summarized above. With respect to claim 12, the patent is deficient in the sense that it does not include heparin in the compositions of the invention.

Moenning teaches combining antiseptic agents with anticoagulants, such as heparin, to reduce risks associated with implantation (See col. 8, lines 22-41).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions disclosed by Dangman et al., by including an anticoagulant, such as heparin, to increase the pharmaceutical activity of the compositions. The expected result would have been a successful composition. Because of the teachings of Dangman et al., that the antiseptic composition may be designed to have a broad spectrum activity against pathogens, and the teachings of Moenning, that anticoagulant, such as heparin, may be combined with antibacterial compositions, one of ordinary skill in the art would have a reasonable

expectation that the compositions claimed in the instant application would be successful against infections and thrombosis. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al. in view of Dangman et al. as applied to claims 1-9, 17-19, 22-30 and 32-35 above, and further in view of Moenning (U.S. Patent 6,063,060).

The teachings of the prior art have been summarized above. With respect to claim 31, the prior art is deficient in the sense that it does not include heparin in the compositions and methods of the invention.

Moenning teaches combining antiseptic agents with anticoagulants, such as heparin, to reduce risks associated with implantation (See col. 8, lines 22-41).
Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions disclosed by Dangman et al., by including an anticoagulant, such as heparin, to increase the pharmaceutical activity of the compositions, and apply said compositions to the catheters disclosed by Burbank et al. The expected result would have been a successful method of devising an implant. Because of the teachings of Burbank et al., that catheters may be equipped with antiseptic compositions, the teachings of Dangman et al., that the antiseptic composition may be designed to have a broad spectrum activity against pathogens, and the teachings of Moenning, that anticoagulant, such as heparin, may be combined

with antibacterial compositions in a medical apparatus, one of ordinary skill in the art would have a reasonable expectation that the method claimed in the instant application would be successful against infections and thrombosis. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

LDN 03

December 11, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600